K113468

DEC 2 0 2011

2.5 *510(k) Summary*

This Special 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:	Creagh Medical IDA Business Park, Ballinasloe, Co. Galway, Ireland
Telephone Number:	011 353 909 646300
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Contact Person:	Eoin McEvoy
Summary Preparation Date:	17th December 2011

2. Device Information

Device Trade Names:	ELM PTA Balloon Dilatation Catheter
Common Name:	PTA Balloon Dilatation Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 870.1250, Product Code: DQY, LIT)

3. Predicate Device

ELM PTA Balloon Dilatation Catheter predicate

Device Name:	ELM PTA Balloon Dilatation Catheter
510(k) Clearance Number:	K102645

4. Device Description

The ELM is a coaxial PTA Balloon Dilatation Catheter with a distal inflatable balloon. One lumen is used for inflation of the balloon with contrast medium; the other lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. Two radiopaque marker bands indicate the dilating section of the balloon and aid in the balloon placement. The marker bands also indicate the nominal length of the balloon. The catheter tip is designed to ease entry into the peripheral arteries and to facilitate the crossing of tight stenoses.

5. Indications for Use

The ELM PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

6. Substantial Equivalence

This Special 510(k) submission aims to demonstrate substantial equivalence of the ELM PTA Balloon Dilatation Catheter with extended range through comparison with the predicate devices – ELM PTA Balloon Dilatation Catheter. The modified device introduces 16 product codes with lower Rated Burst Pressures (RBP) to the existing product matrix. There have been no changes to the intended use, indications or contraindications, as described in the labeling. There have been no other technological changes or changes to the final product specifications other than those noted above with respect to the rated burst pressure. There have been no changes to the sterilization method or to the packaging of the device. Substantial equivalence is demonstrated for the intended use of the ELM device. Where substantial equivalence is not directly demonstrated from the perspective of technology and performance, design verification testing provides evidence of the sbustantial equivalence of the ELM device.

7. Performance Data

The substantial equivalence of the ELM PTA Balloon Dilatation Catheter with extended range to the ELM PTA Balloon Dilatation Catheter cleared in K102645 has been demonstrated through data collected from non-clinical design verification/validation tests and analyses. The devices have been tested according to ISO 10993 Part 1 and were determined to be biocompatible. The following design verification and validation testing was performed:

- Balloon burst and compliance
- Multiple inflation
- Catheter and packaging inspection
- Balloon inflation and deflation
- Bond tensile testing
- Catheter performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 0 2011

Creagh Medical Ltd. c/o
Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K113468
Trade/Device Name: ELM PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Codes: LIT, DQY
Dated: November 18, 2011
Received: November 22, 2011

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

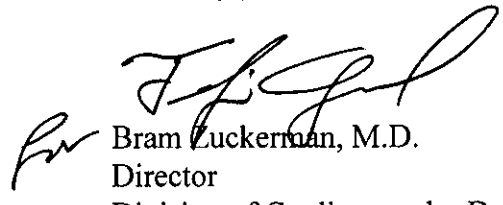
Please be advised that FDA's issuance of a substantial equivalence determination does not mean

that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.4 Indications for Use

510(k) Number (if known): K113468

Device Name: ELM PTA Balloon Dilatation Catheter

Indications For Use:
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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BDE

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113468